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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,769	08/28/2001	James P. Hoeffler	039322-0226	3866

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/28/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/939,769	HOEFFLER ET AL.
	Examiner Anne Holleran	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7,9-22 and 24-53 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 1-7, 9-22, 24-53 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_                    6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, 19-22, 24-29, and 46-53, drawn to methods of screening a DNA construct library, kits, expression vectors, DNA constructs, classified in class 435, subclass 6, class 536, subclass 23.1, 24.33, class, 435, subclass 320.1.
  - II. Claims 9-14, 30-33, drawn to single chain monoclonal antibody fusion reagent, classified in class 530, subclass 387.3.
  - III. Claims 15, 16, 34-37, drawn to therapeutic methods for regulating transcription of a gene, classified in class 514, subclass 44.
  - IV. Claims 17, 38-41, drawn to methods for screening a plurality of compounds for specific binding affinity with a single chain monoclonal antibody fusion reagent, classified in class 435, subclass 7.1.
  - V. Claims 18, 42-45, drawn to methods for diagnosing a physiological disorder, classified in class 435, subclass 7.1 or class 436, subclass 503 and 63.
2. The inventions are distinct, each from the other, for the following reasons:

Inventions I and III are related as product and process of use, because invention I includes products that are also used in the methods of invention III. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of invention group I may be used in the methods of screening of invention group I and in the methods of invention group III. The methods of invention group I are materially different from the methods of invention group III because each method requires separate method steps and results in different outcomes, requiring separate searches.

Inventions II and IV or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of invention group II may be used in either of the methods of inventions IV or V, which are materially different methods of use, requiring different method steps, and separate searches.

Inventions I and II are drawn to separate and independent products (to the extent that Invention I is drawn to products). Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute distinct inventions for the following reasons: The fusion proteins of group II, the polynucleotides of group I, are chemically distinct products unrelated in chemical structure and separately classified, having separate fields of search. The function and existence of DNA and the encoded protein is independent of the function and existence of the other. The products of groups I, and II can be independently synthesized by chemical means. Each of the products has separate, and unrelated

uses. Further, it would place an undue burden on the examiner to examine several, independent inventions in one application.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
January 16, 2003

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ANTHONY C. CAPUTA  
SUPERVISORY PATENT  
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